

CLAIMS

What is claimed is:

1. A method of preventing metastasis in a mammalian subject afflicted with cancer, the method comprising administering to the subject a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof.
2. The method of claim 1 wherein the composition comprises carbohydrate in an amount effective to increase the absorption of glutamine by the subject.
3. A method of preventing recurrence of cancer comprising orally administering to a mammalian subject in remission from cancer or undergoing anti-cancer therapy a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof.
4. The method of claim 3 wherein the composition comprises carbohydrate in an amount effective to increase the absorption of glutamine by the subject.
5. A method of inhibiting the onset of cancer in a mammalian subject at risk of developing cancer comprising orally administering to the subject a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof and carbohydrate in an amount effective to increase the absorption of glutamine by the subject.
6. A method of protecting non-mucosal tissue against damage from radiation therapy, the method comprising:
administering to a mammalian subject afflicted with cancer and treated with radiation therapy a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof, that protects the non-mucosal

tissue against damage from the radiation therapy.

7. The method of claim 6 wherein the composition comprises carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

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8. The method of claim 6 or 7 wherein the composition allows the subject to be treated with a higher dose of radiation and/or treated with radiation for a longer time.

9. The method of claim 6 or 7 wherein the non-mucosal tissue is breast tissue or
10 associated upper body tissue.

10. The method of claim 9 wherein the composition prevents increased breast density or lessens the severity of increased breast density.

15 11. The method of claim 6 or 7 wherein the composition prevents edema or lessens the severity of edema.

12. The method of claim 11 wherein the edema is of breast tissue.

20 13. The method of claim 6 or 7 wherein the non-mucosal tissue is skin.

14. The method of claim 6 or 7 wherein the composition protects the appearance of the non-mucosal tissue.

25 15. A method of protecting skin against damage from chemotherapy, the method comprising:

administering to a mammalian subject afflicted with cancer and treated with chemotherapy a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof, that protects the skin against
30 damage from the chemotherapy.

16. The method of claim 15 wherein the composition comprises carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

5 17. A method of protecting breast tissue against damage from chemotherapy, the method comprising:
administering to a mammalian subject afflicted with cancer and treated with chemotherapy a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof, that protects the breast tissue
10 against damage from the chemotherapy.

18. The method of claim 17 wherein the composition comprises carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

15 19. A method of reducing or preventing pain arising from a non-mucosal tissue, the method comprising:
administering to a mammalian subject afflicted with cancer and treated with chemotherapy and/or radiation therapy a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof, that
20 reduces or prevents pain in the non-mucosal tissue arising from the treatment.

20. The method of claim 19 wherein the composition comprises carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

25 21. The method of claim 19 or 20 wherein the subject is treated with radiation therapy.

22. The method of claim 21 wherein the composition allows the subject to be treated with a higher dose of radiation and/or treated with radiation for a longer time.

23. The method of claim 19 or 20 wherein the subject is treated with chemotherapy and the composition allows the subject to be treated with a higher dose of a chemotherapeutic agent and/or treated with the chemotherapeutic agent for a longer time.

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24. The method of claim 19 or 20 wherein the composition allows the reduction or elimination of the need for further pain control for the subject.

25. The method of claim 19 or 20 wherein the non-mucosal tissue is breast tissue.

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26. The method of claim 19 or 20 wherein the non-mucosal tissue is skin.

27. A method of promoting healing of skin damaged by wound, injury, or infection comprising:

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administering to a mammalian subject a composition comprising a therapeutically effective amount of glutamine or a pharmaceutically acceptable salt thereof, so as to promote healing of non-mucosal tissue damaged by wound, injury, or infection of the skin.

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28. The method of claim 27 wherein the composition comprises carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

29. The method of claim 27 or 28 wherein the non-mucosal tissue is epithelial tissue.

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30. The method of claim 27 or 28 wherein the composition is administered topically.

31. The method of claim 27 or 28 wherein the tissue is damaged by a wound.

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32. The method of claim 31 wherein the wound is an abrasion or laceration.

33. The method of claim 27 or 28 wherein the tissue is damaged by injury, wherein the injury is a burn or ulcer.

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34. The method of claim 33 wherein the injury is a decubitus ulcer.

35. The method of claim 27 or 28 wherein the tissue is damaged by injury, wherein the injury is an insect bite or sting.

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36. The method of claim 27 or 28 wherein the tissue is damaged by bacterial, fungal or viral infection.

37. The method of claim 36 wherein the damaged tissue is a herpetic lesion.

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38. A method of enhancing the effectiveness of chemotherapy and/or radiation therapy, comprising:
administering to a mammalian subject treated for cancer with chemotherapy and/or radiation therapy a therapeutically effective amount of a composition comprising glutamine or a pharmaceutically acceptable salt thereof and carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

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39. A method of increasing the therapeutic index of chemotherapy and/or radiation therapy comprising:
administering to a mammalian subject treated for cancer with chemotherapy and/or radiation therapy a composition comprising (a) glutamine or a pharmaceutically acceptable salt thereof in an amount effective to increase glutathione concentration in at least one normal tissue and decrease glutathione concentration in tumor tissue, thereby reducing the susceptibility of the normal tissue and increasing the susceptibility of the

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tumor tissue to killing by the chemotherapy and/or radiation therapy, and (b)

carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

40. The method of claim 39 wherein the tumor tissue is breast cancer tissue.

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41. A method of promoting apoptosis of cancer cells comprising:
administering to a mammalian subject afflicted with cancer a therapeutically effective amount of a composition comprising glutamine or a pharmaceutically acceptable salt thereof and carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

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42. A method of enhancing natural killer cell activity in a mammalian subject comprising:

15 administering to the subject a composition comprising (a) glutamine or a pharmaceutically acceptable salt thereof in an amount effective to increase natural killer cell activity in the subject and (b) carbohydrate in an amount effective to increase the absorption of glutamine by the subject.

43. The method of claim 42 wherein the subject is afflicted with cancer or HIV.

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44. The method of claim 1, 2, 3, 4, 5, 6, 7, 15, 16, 17, 18, 19, 20, 27, 28, 38, 39, 41, or 42 wherein the amount of glutamine administered is at least 0.5 mg per day per kg body mass of the subject.

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45. The method of claim 44 wherein the amount of glutamine administered is 0.2 g to 3.0 g per day per kg body mass of the subject.

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46. The method of claim 1, 2, 3, 4, 5, 6, 7, 15, 16, 17, 18, 19, 20, 27, 28, 38, 39, 41, or 42 wherein the amount of glutamine administered to the subject is less than 0.5 g per kg per day.

47. The method of claim 1, 2, 3, 4, 5, 6, 7, 15, 16, 17, 18, 19, 20, 27, 28, 38, 39, 41, or 42 wherein the amount of glutamine administered to the subject is less than 0.1 g per kg per day.

5 48. The method of claim 2, 4, 5, 7, 16, 18, 20, 28, 38, 39, 41, or 42 wherein the carbohydrate comprises one or more monosaccharides or disaccharides.

49. The method of claim 2, 4, 5, 7, 16, 18, 20, 28, 38, 39, 41, or 42 wherein the carbohydrate comprises a sugar alcohol.

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50. The method of claim 2, 4, 5, 7, 16, 18, 20, 28, 38, 39, 41, or 42 wherein the weight ratio of total carbohydrate to glutamine in the composition is 0.5:1 to 50:1.

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51. The method of claim 2, 4, 5, 7, 16, 18, 20, 28, 38, 39, 41, or 42 wherein the weight ratio of total carbohydrate to glutamine is at least 4:1 in an aqueous solution, either after preparation with an aqueous solvent or after delivery in an aqueous environment of the mammalian subject.

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52. The method of claim 1, 2, 3, 4, 5, 6, 7, 15, 16, 17, 18, 19, 20, 27, 28, 38, 39, 41, or 42 wherein the composition comprises no more than 5 naturally occurring amino acids other than glutamine.

53. The method of claim 52 wherein the composition comprises no naturally occurring amino acids other than glutamine.

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54. The method of claim 1, 2, 6, 7, 15, 16, 17, 18, 19, 20, 27, 28, 38, 39, 41, or 42 wherein the composition is administered orally.

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55. The method of claim 1, 2, 3, 4, 5, 6, 7, 15, 16, 17, 18, 19, 20, 27, 28, 38, 39, 41, or 42 wherein the mammalian subject is a human.

56. The method of claim 1, 2, 3, 4, 6, 7, 19, 20, 38, 39, 41, or 42 wherein the composition is administered after or while administering radiation therapy to the subject.

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57. The method of claim 6, 7, 19, 20, 38, 39, 41, or 42 wherein the composition is administered before administering radiation therapy to the subject.

58. The method of claim 1, 2, 3, 4, 15, 16, 17, 18, 19, 20, 38, 39, 41, or 42 wherein
10 the composition is administered after or while administering chemotherapy to the subject.

59. The method of claim 1, 2, 3, 4, 41, or 42 wherein the composition is administered after or before surgically treating the subject for cancer.

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60. The method of claim 1, 2, 3, 4, 41, or 42 wherein the composition is administered after or while treating the subject for cancer with a biological agent.